

Exhibit E

In re: National Prescription Opiate Litigation MDL no. 2804
Case No. 17-md-2804

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Preface

I have been retained by counsel for Montgomery County, Ohio in the National Prescription Opiate Litigation to analyze the workload surveys conducted by the Ohio Board of Pharmacy and to assess the report submitted by Dr. J. Ann Selzer on behalf of defendant The Kroger Company.

Background and Experience.

I currently serve as a Professor at the University of Arizona Osher Lifelong Learning Institute in Tucson, Arizona. I also am Dean Emeritus and Professor at the University of Kansas School of Pharmacy in Lawrence, Kansas.

I graduated from the University of Nebraska Medical Center College of Pharmacy in 1975. Between 1980 and 1983, I was a Kellogg Pharmaceutical Clinical Scientist Fellow at the University of Minnesota where I obtained my Ph.D. in Social and Administrative Pharmacy. In 2006, I received a post-graduate certificate degree in Health Economics within the Heath Economics Research Unit from the University of Aberdeen, Aberdeen, Scotland

I have been a professor and administrator at several Universities and Colleges of Pharmacy and Public Health for 36 years and have delivered courses in Doctor of Pharmacy and graduate school program curricula. From 1994 to 2004, I served as dean of the University of Kansas School of Pharmacy. My coursework has included the U.S. Healthcare System; Introduction to Public Health; Research Design and Methods; and Public Health and the Health Professions. In these courses, modules have focused on source, price, promotion, products, and the channel of distribution for pharmaceuticals in the U.S. healthcare system. In the pharmacy practice management course, I have taught Doctor of Pharmacy Students the skills necessary to practice pharmacy in both outpatient community pharmacy (including dispensing and promotion good pharmacy practices) and health care systems practice; and I presented materials on marketing and pharmaceutical marketing within the U.S. healthcare system. I have taught research design and methods courses for both master's and Ph.D. students in colleges of pharmacy and public health. In these graduate level courses in colleges

of pharmacy and public health I taught research methods courses that involved research design focusing on survey research and questionnaire design. These courses also involved the use of statistical analytic techniques, both qualitative and quantitative in nature. I have also served as an advisor for Master and PhD students, for which their theses involved questionnaire design, survey research methods, and data analysis. The statistical analytic software that I have used in teaching and research for data analysis include SAS, SPSS, and STATA. I was one of the first college of pharmacy faculty in the U.S. to incorporate into my school of pharmacy course materials the Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Pain-United States.¹

I have researched various topics pertaining to medication management, the U.S. healthcare system, marketing of pharmaceuticals in the U.S. and abroad, avoiding medication risks, patient compliance, and drug use by seniors. During my tenure at the University of Kansas, I was the principal investigator and director of the State of Kansas Medicaid Drug Utilization Review Program (DUR) financed by the U.S. Centers for Medicare and Medicaid Services (CMS) and the State of Kansas from 1998 through 2003.

I have published 255 papers in refereed journals focused on pharmacy, medicine, public health, nursing, adverse drug reactions (pharmacoepidemiology), health care economics (pharmacoeconomics), health outcomes, and related disciplines. These papers I have written have been cited by other authors in published papers a total of 3,414 times. My author h-index is 23.² My author i10-index is 48.³ A total of 70 of these refereed publications have been the result of questionnaire and survey research, these manuscripts have been published in national and international peer reviewed journals. Two of these publications written on survey research and methods have been cited by other authors 1,500 times. I have presented my research, including issues pertaining to pharmacy practice and pharmaceutical marketing in Australia, Canada, the United Kingdom, the United States, Taiwan, Turkey, and Vietnam. I have been the founding editor of two scholarly journals and serve or have served on the editorial board of 10 journals. During my ten years' service as an associate editor for the *American Journal of Pharmaceutical Education* when issues of survey research or questionnaire design were brought forward, the issues were always referred to me.

¹ Dowell D, Ragan KR, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain-United States, 2022. MMWR Recomm Rep 2022; (No.RR-3): 1-95. DOI:

https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.

Accessed 5 February 2023.

² The h-index is a measure used to indicate the impact and productivity of a researcher based on how often publications have been cited, in this case 23 papers have been cited 23 times.

³ The i10-index is a measure used to indicate how many publications have been cited 10 times by other published manuscripts, on this case 48 papers have been cited 10 times.

Because of my expertise in research design and methods and outcomes research and subsequent publication, I have been asked to serve as an external portfolio reviewer for well over 100 individuals seeking promotion and tenure at academic colleges of pharmacy, medicine, and public health in the United States. Many of these associate or full professor candidates involved research they conducted and published dealing with survey and survey research and methods.

I have edited and written 13 books. The text, *Pharmacy and the U.S. Healthcare System* is in its fourth edition, and previous editions have been used in many Pharmacy Administration courses covering the U.S. Healthcare System. It has been the singular textbook most utilized in such courses since 1991.

I have served as a consultant for the U.S. Centers for Medicare and Medicaid Services (CMS) as an expert on the pharmaceutical industry in the U.S. to help educate CMS personnel on how the drug use process works in the U.S. In these training programs for each of the ten CMS regions in the U.S., I extensively detail how marketing, pricing, and the channels of distribution within the U.S. healthcare system affect the distribution of pharmaceuticals, the prescribing of drugs, the varying payment systems for expenditures for drugs, and policy issues surrounding the marketing and delivery of pharmaceuticals.

Between 1987 and 1989, I was the principal investigator for a U.S. Food and Drug Administration's pilot program developing an adverse drug reaction program for the State of Mississippi. The results of this grant led to the development of an online adverse drug reaction reporting program using computer entry of data. This successful grant also led to the development of the current online database for adverse drug reaction reporting in the U.S. The system is known as the FDA Adverse Event Reporting System (FAERS).

The national leadership of CMS invited me to present retail pharmacy perspective on the Medicare Drug Discount Card program in their kick-off conference highlighting the impending beginning of the Medicare Drug Discount Care Program in Washington, D.C., in February 2004.

I have received research funding of over \$3.42 million in my career. These funds have come from grants and contracts with the U.S. Department of Health and Human Services (Food and Drug Administration, Centers for Medicare and Medicaid Services), the U.S. National Science Foundation, states, foundations, national organizations, and other funding sources.

I currently serve as a member of two U.S. Food and Drug Administration Advisory Committees: Nonprescription Drug Advisory Committee (NDAC) (since 2003) and the Peripheral and Central Nervous System Drugs (since 2017).

Since 2011, I have been invited to serve as an invited study section panel member for the Canadian Institutes of Health Research (CIHR) Drug Safety and Effectiveness Network (DESN); in 2014, I served as Chair of the Peer Review

Committee for the CIHR DESN Collaborating Centers. In 2017, I was an invited study section chair for the CIHR Project Scheme (CIHR/IRSC). Also in 2017, I was appointed as an Invited Member of the CIHR College of Reviewers advancing peer review excellence, for which this appointment runs through 2026.

I have served as an expert witness and been deposed in numerous cases over the past 20 years. In these cases, I have been retained by attorneys representing both plaintiffs and defendants. Beginning in 2001, I served as an expert witness for pharmacy standard of care lawsuits in Kansas City, MO, and the Robert Courtney cancer chemotherapy criminal dilution lawsuit also in Kansas City, MO. I was also retained and produced an expert report for a trademark infringement lawsuit (*Atley Pharmaceuticals, Inc. vs. Brighton Pharmaceuticals, Inc. et al.*) in 2006. I served as a consulting expert for the *Plubell and Ivy vs. Merck and Company* (VIOXX) litigation in Kansas City, Missouri, 2011.

In the past five years, I was deposed in *Vanzant, et al. v. Hill's Pet Nutrition, et al.*, USDC ND Ill., Case No. 1:17-cv-02535 and testified at trial in 2019 in *South Carolina v. Pamela Tackett*, Indictment Nos. 2018-2360308570, -571, -572, 2018a-3010200084. A list of cases in which I have testified in the last 4 years is attached as Attachment A.

The opinions expressed in this report are based on my experience as a pharmacist (educator and practitioner) over the past 48 years; my Ph.D. studies including all the courses I attended to obtain my degrees and subsequent degrees and graduate courses; my research and writing experiences in the areas of drug use, marketing of pharmaceuticals, survey design, implementation and analysis public health, pharmacy industry practice; and my review of case related materials in the preparation of this report. I have practiced pharmacy in independent ambulatory pharmacies (one of which I was a co-owner), at chain community pharmacies, a long-term care consultant pharmacy, and institutional pharmacies (pediatric and adult intensive care units, inpatient pharmacies, and volunteering in a COVID-19 vaccination drive through vaccination site where I prepared over 15,000 COVID-19 individual doses for injection).

I am being compensated for my time at a rate of \$350 per hour, plus expenses. I do not have any financial stake in the outcome of this litigation. My current curriculum vitae is attached as Attachment B. The materials I considered in forming my opinions is attached as Attachment C.

Assignment and Summary of Opinions

I have been asked to review and analyze the Ohio Board of Pharmacy's 2020 and 2021 pharmacy workload surveys and the report submitted by Dr. J. Ann Selzer⁴ on behalf of The Kroger Company. Dr. Selzer offers two overarching

⁴ Evaluation of 2021 Pharmacist Workload Survey Conducted by the State of Ohio Board of Pharmacy, J. Ann Selzer, Ph.D. (hereinafter "Selzer Report").

criticisms of the Ohio Board of Pharmacy Surveys. First, she questioned “the usefulness of this [2021] survey in understanding the role of pharmacists and pharmacies in opioid abuse and diversion.”⁵ Next, Dr. Selzer believes methodological flaws in how survey response were “tabulated” does not allow for an understanding of all Ohio pharmacists’ beliefs, such that the “survey on workplace concerns does not substitute for a valid measurement of pharmacists’ views of opioid misuse and diversion, including how they are dispensing opioids in Ohio.”⁶ She criticizes the lack of data available to her to determine whether the opinions expressed in the data reflect a larger pool than the 2,969 licensed pharmacists working in Ohio who completed the survey. She questions whether the pharmacist’s responses can be generalizable beyond those who completed the survey.⁷

In my opinion, the Ohio Board of Pharmacy surveys collected sufficient and reliable information from those Ohio pharmacists working in large chain grocery store settings that, when placed in the context of the opioid epidemic, identify serious concerns about the safe and effective dispensing of opioids among other medications.

Overview of the Ohio Board of Pharmacy Surveys

Pharmacies and pharmacists are regulated by state board of pharmacies. The Ohio Board of Pharmacy “is responsible for regulating the practice of pharmacy as well as the distribution of dangerous drugs...”⁸ The purpose of the Ohio Board of Pharmacy, like other state boards, is “to safeguard the public [and] to ensure the safe practice of pharmacy in the state.”⁹

Over the last twenty years, there has been a growing concern among pharmacists, boards of pharmacy and trade associations related to working conditions in retail chain and grocery store pharmacies. These concerns have been identified in complaints issued to state pharmacy boards by pharmacists, in DEA cases which have warned about pharmacies utilizing metrics and other incentives to reward pharmacists filling controlled substance prescriptions. Warnings from the National Association of the Board of Pharmacy and reporting in national newspapers on the incidence of dispensing errors identify inadequate

⁵ Selzer Report, p. 2.

⁶ Ibid.

⁷ Ibid.

⁸ November 3, 2022, Deposition of Cameron McNamee (hereinafter “McNamee Dep.”), p. 14:14-22.

⁹ McNamee Dep. 15:23-16:3.

staffing¹⁰, pharmacist workloads and the use of metrics, which incentivize speed over patient safety, as primary causes of unsafe pharmacy practice.¹¹ These concerns were clearly a motivating factor in the Ohio Board of Pharmacy's decision to issue a workload survey to its pharmacists in 2020. In fact, the Ohio Board of Pharmacy specifically referenced these sources as the basis for seeking a survey of pharmacists in Ohio.¹²

Ohio was not alone as other state boards of pharmacies from Missouri, Tennessee, Maryland, among others, issued similar workload surveys to its pharmacists due to the growing national concern with pharmacy working conditions.¹³ Surveys were also conducted by the American Association of Pharmacists in 2014 and 2019 where pharmacists reported "highly stressful" working conditions related to workloads, staffing and the potential for safe patient care and medication errors.¹⁴

There is also peer-reviewed literature which described concerns for pharmacist working conditions.¹⁵ The Ohio Board of Pharmacy noted three specific studies linking increasing workload demands with patient safety.¹⁶

¹⁰ NABP, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), <https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/>; Sam Roe, *Pharmacies miss half of dangerous drug combinations*, Chicago Tribune, Dec. 15, 2016, (McNamee, Ex. 5); Ellen Gabler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, New York Times, Jan. 31 (McNamee Ex. 6); See also, NACDS_FL_0024875 (article titled "Are more mistakes happening at pharmacies?"); NACDS_FL_0024888 (article titled "Risks Inherent in Pharmacists' Workloads Earn Attention of Legislators").

¹¹ OBOP_0002207 at OBOP_0002208 (McNamee Ex 4).

¹² McNamee Dep. 40:4-41:3.

¹³ OBOP_0002207 (McNamee Ex 4); OBOP_00000112 (McNamee Ex. 10)

¹⁴ OBOP_0002207 at 2208 (McNamee Ex 4); 2014 National Pharmacist Workforce Survey, Final Report of the 2014 National Sample Survey of the Pharmacist Workforce to Determine Contemporary Demographic Practice Characteristics and Quality of Work-Life, April 8, 2015 (McNamee Ex. 7); National Pharmacist Workforce Study 2019, https://www.aacp.org/sites/default/files/2020-03/2019_NPWS_Final_Report.pdf (McNamee Ex. 8).

¹⁵ See, for example, Clabaugh M, Newlon JL, Illingworth Plake KS. Perceptions of working conditions and safety concerns in community pharmacy. *J Am Pharm Assoc.* 2021 Nov-Dec;61(6):761-771. doi: 10.1016/j.japh.2021.06.011. Epub 2021 Jun 12. PMID: 34176759; Newlon JL, Clabaugh M, Illingworth Plake KS. Policy solutions to address community pharmacy working conditions. *J Am Pharm Assoc* (2003). 2021 Jul-Aug;61(4):450-461. doi: 10.1016/j.japh.2021.02.011. Epub 2021 Feb 26. PMID: 33722541; Dilliard R, Hagemeier NE, Ratliff B, Maloney R. An analysis of pharmacists' workplace patient safety perceptions across practice setting and role characteristics. *Explor Res Clin Soc Pharm.* 2021 Jun 29;2:100042. doi: 10.1016/j.rcsop.2021.100042. PMID: 35481120; PMCID: PMC9031369.

¹⁶ OBOP_0000112-OBOP_0000113 (McNamee Ex. 10), citing Shao SC, Chan YY, Lin SJ, Li CY, Kao Yang YH, Chen YH, Chen HY, Lai EC. Workload of pharmacists and the

The surveys also supported the evaluation of Ohio specific regulations concerning adequate staffing and safe working conditions in pharmacies:

ORC 4729.55 states the following:

(D) Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.

- Rules 4729:5-5-02 and 4729:5-9-02.1 (pending) of the Administrative Code which state: The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code.

The Ohio Board of Pharmacy is charged with ensuring compliance with these regulatory obligations¹⁷ and the workload surveys were issued by the Board to all licensed pharmacists in Ohio pursuant to this regulatory authority.¹⁸ In fact, a number of the questions in the surveys specifically incorporate this regulatory language. Example survey questions include:

- Q1. I feel that I have adequate time to complete my job in a safe and effective manner.¹⁹
- Q2. I feel that my employer provides a work environment that allows for safe patient care.²⁰
- Q3. I feel that my work environment has sufficient pharmacist staffing that allows for safe patient care.²¹
- Q4. I feel that my work environment has sufficient pharmacy technician staffing that allows for safe patient care.²²

performance of pharmacy services. PLoS One. 2020 Apr 21;15(4):e0231482. doi: 10.1371/journal.pone.0231482. PMID: 32315319; PMCID: PMC717387, Malone, Daniel C., et al. "Pharmacist Workload and Pharmacy Characteristics Associated with the Dispensing of Potentially Clinically Important Drug-Drug Interactions." Medical Care, vol. 45, no. 5, 2007, pp. 456–62. JSTOR, <http://www.jstor.org/stable/40221447>. Accessed 16 Feb. 2023, and Pervanas HC, Revell N, Alotaibi AF. Evaluation of Medication Errors in Community Pharmacy Settings: A Retrospective Report. J Pharm Technol. 2016 Apr;32(2):71-74. doi: 10.1177/8755122515617199. Epub 2015 Nov 18. PMID: 34861023; PMCID: PMC5998534.

¹⁷ OBOP_0000112 (McNamee Ex. 10)

¹⁸ Ibid.

¹⁹ OBOP_0000112 at OBOP_0000117OBOP_0000290 at 294-298.

²⁰ OBOP_0000112 at OBOP_0000119

²¹ OBOP_0000112 at OBOP_0000121; OBOP_0000290 at 299-303.

²² OBOP_0000112 at OBOP_0000123; OBOP_0000290 at 304-308.

Q6. I feel pressure by my employer or supervisor to meet standards or metrics that may interfere with safe patient care.²³

Q7. I feel that the workload to staff ratio allows me to provide for patients in a safe manner.²⁴

Respondents were asked with respect to each question whether they strongly agree, agree, are neutral, disagree, or strongly disagree. The Board intentionally referenced the regulatory language in framing these questions because the Board was concerned with compliance with these regulatory sections by Kroger and other pharmacies operating in the state.²⁵ It is important to note that the respondents, licensed pharmacists in Ohio, were responding to a survey issued by their regulator. In my opinion, pharmacists were more likely to provide truthful responses to the surveys viewing them as sincere efforts to understand pharmacists' perceptions of how their workloads impact patient safety. Some of the written comments specifically requested that the Board take action to improve working conditions and patient safety.²⁶.

Dr. Selzer's Assessment and Comments Regarding the Ohio Board of Pharmacy Workload Surveys

Organizations conduct different types of surveys for different purposes. The Ohio Board of Pharmacy conducted its surveys to gather information about existing workload concerns that required further study, and not necessarily to understand what all Ohio pharmacists believed. Organizations often conduct surveys to identify perceptions, track trends, or gauge the strength of impressions. Surveys of this kind are often conducted to direct further study.

²³ OBOP_0000112 at OBOP_0000127; OBOP_0000290 at 314-318.

²⁴ OBOP_0000112 at OBOP_0000129; OBOP_0000290 at 319-323.

²⁵ McNamee Dep. P. 55:17 –56:9.

²⁶ See, for example, OBOP_0000112 at OBOP_000199 (“I work a 13 hour shift once every week as the only pharmacist. I am ‘lucky’ to get 10 minutes the whole shift to have a break to eat. There are some days this doesn’t happen at all. This is so unsafe! Something needs to be done in the state of Ohio to make it safe for our patients. After checking 400 prescriptions alone you lose your focus. I have been a pharmacist for 20 years and things continue to worsen for retail pharmacists. We are all afraid to say anything in fear of losing our jobs. Please help all of us out and bring joy to our jobs once again. I went to pharmacy school to help patients live healthier lives not worrying about metrics and silly programs to make money for the company I work for.”) or at OBOP_0000241 (“Please help fix this retail problem. Our patient safety is no longer a major concern at the retail level. It’s all about metrics and money. Please bring back our profession to its trustworthy safe glory. We need more time to process prescriptions safely.”)

It has long been known and appreciated in the practice of pharmacy that workloads can impact patient safety. The surveys issued by the Ohio Board of Pharmacy were intended to “assess where we are as a state [on workload impacts], and, two, depending on the responses, trying to come up with some policy solutions to address these issues.”²⁷ The survey confirmed, according to Ohio pharmacists that responded, that the trend of workload demands continues to impact patient safety, it identified the sources of concerns, and gathered important information about the severity of the concerns. The results according to the Board were striking²⁸

It is important to note that Dr. Selzer and I agree on a majority of issues, particularly as to the results of the surveys. For example, Dr. Selzer and I agree that the Ohio Board of Pharmacy was reasonable in issuing a workplace survey to pharmacists in Ohio.²⁹ We also agree that the Board of Pharmacy sought and received truthful answers in the survey,³⁰ and that there was no evidence of fraud or manipulation of the survey.³¹ She also agreed that she had no particular criticisms with the questions that were asked in the survey or the manner in which the questions were asked.³² For instance, we both agree that it was appropriate and beneficial for the Board to send the survey to Ohio pharmacists using the e-mail addresses provided to the Board in a secure link and to seek anonymous responses.³³ We agree that if the responses are anonymous it would be more likely that respondents would answer more honestly.³⁴ We also agree that using a Likert five-point scale to rate pharmacists’ perceptions of the workplace was appropriate and that the questions were not biased or suggestive of an answer.³⁵ In fact, she concludes, and I agree, that the “2021 survey is a valid attempt to understand workplace issues among licensed pharmacists working in Ohio.”³⁶

Many of Dr. Selzer’s criticisms are framed as indirect attacks on the surveys’ methodology calling for more information to determine whether the methodology used was appropriate. For example, she states “[t]his survey, like many other contemporary surveys, faces problems of non-response.”³⁷ She admits in her deposition, that she will not offer an opinion that the response rate to the Ohio

²⁷ McNamee Dep., 250:22-251.

²⁸ McNamee Dep., 120:18-25 (“Q. What did you mean here when you used the word “striking” with respect to the data responses to the workload survey? A. Essentially that there was -- you know, the data presented a considerable issue, and so that’s why it was -- it was pretty striking to myself, as well as the staff, when we reviewed it.”)

²⁹ January 20, 2023, Deposition of J. Ann Selzer (herein after “Selzer Dep.”) p. 103:24.

³⁰ *Ibid.* p. 104:3-11.

³¹ *Ibid.* p. 91:4 -20 *see also*, McNamee Dep. p. 134: 8 – 14, p. 158: 20-23.

³² *Ibid.* p. 105: 9.

³³ *Ibid.*, p. 152: 22 – p. 153:9.

³⁴ *Ibid.* p. 153: 10 – 14.

³⁵ *Ibid.*, p. 105: 10 – 17.

³⁶ Selzer Report, p. 4.

³⁷ *Ibid.*, p. 12.

Board of Pharmacy surveys was so low that it discredits the surveys.³⁸ In fact, she noted that in phone surveys the typical response rate is in the low single digits. In a *JAMA* paper written a decade ago (and referenced by other published authors 720 times¹), Johnson and Wislar suggest that assessments of research studies have “concluded that the response rate of a survey may not be as strongly associated with the quality or representativeness of the survey as had been generally believed.”³⁹ In my opinion the response rate for pharmacists responding to the 2020 and 2021 survey was adequate and appropriate. Similar surveys assessing the status of the work environment for pharmacists have been conducted with similar response rates.

In addition to the response rate, there was a similarity in responses between the 2020 survey and the 2021 survey issued by the Board. Dr. Selzer is critical of the surveys change in the number of large chain grocer pharmacists who responded between 2020 and 2021.⁴⁰ In 2020, 1,000 pharmacists identified themselves as working in “large chain grocer” setting. In 2021, 1,071 pharmacists identified themselves as working in “large chain grocer/ box store.” Dr. Selzer, characterizes the change in the number of pharmacists responding in this work setting by comparing their relative share to each year’s total respondents and contemplates the difference:

We do know that, proportionately, this was an increase of 50% for respondents in this setting. It was 24% of responding pharmacists in 2020 and 36% in 2021. We have no data to explain the increase. We cannot judge which year is a more appropriate representation of this subgroup of pharmacists. Maybe neither is. Maybe both are because of real changes in the pharmacists’ employment.⁴¹

Dr. Selzer’s analysis is somewhat misleading by choosing to express the year-over-year change in large chain grocer respondents proportionally as share of the total respondents. The numerical difference is 71, (1,071-1,000) an increase of about 7% between 2020 and 2021.

There are some reasonable explanations for why a “follow-up” survey in 2021 had more respondents, but Dr. Selzer does not consider this question, nor does she take the time to contemplate the surveys’ purpose as intended by the Board of Pharmacy. Had Dr. Selzer looked, she may have begun to answer her other questions by reviewing the Ohio Board of Pharmacy’s annual reports which report increases in new pharmacists between 2020 and 2021.⁴² Nevertheless, a 7%

³⁸ Selzer Dep. P. 162: 17 – 21.

³⁹ Johnson TP, Wislar JS. Response rates and nonresponse errors in surveys. *Jama*. 2012 May 2;307(17):1805-6.

⁴⁰ Selzer report, pp. 14-15.

⁴¹ Selzer Report, p. 15.

⁴² See FY 2020 Annual Report, p.3 at

<https://www.pharmacy.ohio.gov/documents/pubs/reports/annualreports/fy%202020%>

increase in the number of respondents in large chain grocery stores is not concerning. In my opinion it shows a certain level of consistency.

What is significant for the Board and its purposes, is that the 2020 survey was not an anomaly, respondents in both surveys consistently expressed concerns about safe and effective patient care in the large grocery store sector. In fact, the pharmacist views grew worse reflecting a deteriorating environment in the large chain grocer pharmacists' working conditions. Using Dr. Selzer's numbers, a growing alarm is expressed by large chain grocery pharmacists. For example, on the question "I feel that my work environment has sufficient pharmacist staffing that allows for safe patient care", in 2020 37% of large chain pharmacists disagreed with the statement while 27% disagreed strongly. This resulted in a combined percentage of 64%. In 2021, 34% of large chain grocery pharmacists disagreed with the statement and 48% strongly disagreed, for a combined 82% who disagreed.⁴³

This increase in both the number of concerns and intensity of beliefs can be seen in other questions answered by large chain grocery store pharmacists between 2020 and 2021. At a practical level, the Board not only confirmed that large chain grocery store pharmacists feel that their working conditions interfere with safe patient care, it learned that these feelings were increasing rather than decreasing over time. The Board publicly released the results of the 2020 survey. It is not apparent that large chain grocery stores made any effective changes to their policies and procedures to alleviate pharmacist concerns. In fact, as reflected in the 2021 survey those perceptions grew worse among pharmacists that responded to the survey.

As one chosen to evaluate the validity of a survey, several questions must be answered to gain an appreciation of the totality of the survey and its worthiness. The most important of the questions is "what is the purpose that the survey, why is it important to administer the survey, and how will the survey results be used."⁴⁴ Surveys are conducted for a variety of purposes and failing to determine the purpose of a survey and how it will be used deprives the reviewer of important context in evaluating the results and the appropriateness of the technique. In my opinion, the surveys conducted by the Ohio Board of Pharmacy were valid and appropriate especially when evaluated for their purpose and use.

[20annual%20report.pdf](#) and FY 2021 and 2022 Annual Report, p. 4

<https://www.pharmacy.ohio.gov/documents/pubs/reports/annualreports/fy%202021%20and%202022%20annual%20report.pdf>

⁴³ Selzer Appendix, p. X-19

⁴⁴ Dilman DA, Smyth JD, Christian LM. Internet, phone, mail, and mixed-mode surveys: The tailored design method. John Wiley & Sons; 2014 Aug 18. Additional questions include the type of survey to be utilized such as a paper and pencil or web based survey, the sample size for the survey, who are the subjects of the survey and what specific characteristics do they have? And will the questionnaire be a Likert scale, an open-ended set of questions or both.

Dr. Selzer admitted in her deposition that it was not her assignment to analyze why the Ohio Board of Pharmacy conducted the workload surveys.⁴⁵ She also did not seek to understand the importance of the survey or how the Board of Pharmacy utilized the survey results.⁴⁶ Understanding the purpose of the survey and how it is to be used is critical to determining whether the results of the survey are reliable for the purposes that the survey was being conducted. Even though Dr. Selzer claims it was not part of her assignment she nevertheless offers an opinion as to "the usefulness of this survey in understanding the role of pharmacists and pharmacies in opioid abuse and diversion."⁴⁷ She concluded that:

This survey does not provide data on that topic—it is not a survey about pharmacists' and pharmacies' roles in opioid abuse and diversion. There were no questions about opioids. There were no questions about patient requests for controlled substances. There were no questions about procedures pharmacists follow when dispensing controlled substances. While the survey asks about patient safety across several questions, it would be an unsubstantiated leap to believe the answers to these questions reflect pharmacists' specific concerns with the dispensing of opioids. Some pharmacists may have concerns about that, but this survey did not purport to measure that, nor do we have evidence this was what pharmacists had in mind as they answered questions.⁴⁸

It is misleading to suggest that only literal questions and answers about opioids can yield insights into the role of pharmacists and opioid abuse. Dr. Selzer is primarily a political pollster and lacks the experience and expertise in pharmacy operations, controlled substance dispensing, and opioid abuse and diversion to interpret how some pharmacists' concerns about workloads would impact dispensing of controlled substances. As Dr. Selzer acknowledges, her assignment from Kroger did not include "looking at what the overall findings say and then to dissect whether there certain subgroups who have different opinions, who are aligned in a different way, to get a more rich understanding of why the data look like they do, not just what the data say."⁴⁹ A complete analysis includes interpreting the survey results and pharmacists' comments in the context of pharmacy practice, policy, and regulations imposed on pharmacists, which Dr. Selzer was not asked or qualified to perform. And yet, doing so, offers obvious insights into how pharmacy workloads impact the safe dispensing of controlled substances, including opioids.

Furthermore, Dr. Selzer's methodological concerns about the survey are not directly relevant to the survey's purpose and, by her admission, do not invalidate

⁴⁵ Selzer Dep. p. 96: 20- 22.

⁴⁶ Ibid. p. 106:5- 13 (Selzer admits that she did not examine any steps that the Ohio Board of Pharmacy took in response to the survey results).

⁴⁷ Selzer Report, p. 2

⁴⁸ Ibid.

⁴⁹ Selzer Dep., p. 193.

the survey results.⁵⁰ The Ohio Board of Pharmacy's mission is safeguarding patients, and the survey intended to gather information about whether Ohio pharmacists believe patients were at risk because of pharmacy workload demands.⁵¹ For the Board, the survey gathered significant evidence that many pharmacists' workloads impacted their ability to safely and effectively perform their duties, and thus patient safety was at risk. According to the regulator, that evidence was of sufficient credibility and quantity for the Board to act to protect patients. Dr. Selzer's purpose was to determine whether the responses to the survey "are or are not an accurate cross-section of all licensed pharmacists working in Ohio."⁵² The survey did not need to gather a representative view of all Ohio pharmacists for the Board to act, and Dr. Selzer assumed a purpose for the survey for which it was not intended.

Interpreting the pharmacy workload survey results fell outside Dr. Selzer's assignment and expertise. Crucially, Dr. Selzer does not know enough about the relevant aspects of pharmacy operations, dispensing regulations, or opioid abuse and diversion to interpret the survey results. For pharmacists, section 1306.04(a) "Purpose of issue of prescription" of the Controlled Substances Act of 1970 lies at the center of federal and state regulations defining the responsibilities of controlled substances dispensing. This section, often referred to as the "corresponding responsibility," states:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.⁵³

Pharmacies that are licensed registrants under the Controlled Substances Act and pharmacists that dispense controlled substances are keenly aware of their responsibilities to ensure that before a controlled substance is dispensed the prescription was written in the "usual course of professional treatment" and that

⁵⁰ See, for example, Selzer Dep., pp 158:13-21, 159:15-19, and 160:20-162:21.

⁵¹ Ohio Board of Pharmacy, "Pharmacists Workload Survey," April 2021, p. 4 ("The intent of the survey was to capture vital feedback on pharmacist working conditions in the state.")

⁵² Selzer Report, p. 3.

⁵³ Title 21 Chapter II Part 1306 General Information § 1306.04

all controlled substances dispensed must be “for a legitimate medical purpose.” The pharmacy and its pharmacists have an independent responsibility from the prescriber to assess whether the controlled substance prescription should be dispensed. This is a very serious responsibility. The Controlled Substances Act and state regulations seek to create a closed system to protect the public from misuse and diversion of dangerous drugs.

Opioids such as oxycodone and hydrocodone are Schedule II drugs which are defined in the Act as “drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.”⁵⁴ The risk of diversion with respect to opioids has increased significantly across the United States. The CDC has described the opioid crisis in the U.S. as an epidemic.⁵⁵ Every state has been impacted by the opioid epidemic including Ohio. Ohio has suffered more overdose deaths than most other states across the country as a result of opioids.⁵⁶ In fact, unintentional overdose was the leading cause of death in Ohio in 2017.⁵⁷ The Board of Pharmacy recognized that “pharmacists have a unique role to play in the front lines of the opioid epidemic.”⁵⁸ The Ohio Board of Pharmacy evaluated the characteristics of unintentional overdoses and found significant connections between prescriptions opioids, controlled substance use and overdose deaths. For example, in 2014, the Board determined that 42% of all overdoses had a daily MME of 80 or above in the past.⁵⁹ The Ohio Board also determined that 44% of those who overdosed had a prescription for a benzodiazepine with 90 days of death. For about 30% of all unintentional overdose deaths that year involved both an opioid and benzodiazepine prescription.⁶⁰ These statistical findings implicate prescription opioids and other controlled substances as increasing the risk of overdose. Dangerous drugs obtained through licensed pharmacies contributed to the state’s opioid epidemic. For the Board, the question is not if pharmacies play a role in opioid abuse and diversion but why they play role and whether enhanced regulations and changes in corporate conduct may reduce the risk of abuse and diversion.

Pharmacists are keenly aware they must protect patients. The inherent danger of controlled substances, the regulatory guidance to address these dangers, and the significant additional due diligence that pharmacist must perform to dispense controlled substances are linked to “safe and effective” patient care for pharmacists. Pharmacists understand and fulfill their controlled substance obligations knowing that dispensing controlled substances is potentially the most dangerous aspect of pharmacy practice, and to suggest that patient safety would

⁵⁴ Title 21 Chapter II Part 1308, Schedule II § 1308.12

⁵⁵ US CDC. <https://www.cdc.gov/opioids/basics/epidemic.html>, accessed 5 February 2023.

⁵⁶ McNamee Dep. p. 17: 12-22:7; BOP_MDL1252485 (McNamee Ex 2).

⁵⁷ Ibid. p. 20:7- 20.

⁵⁸ McNamee Dep. 22:8-14.

⁵⁹ Ibid. p. 196:6 – 197:12.

⁶⁰ Ibid. p. 197:13 – 198:25.

not encompasses filling dangerous opioid prescriptions ignores why and how pharmacists protect patients.

How pharmacists protect patients starts with exercising corresponding responsibility. The exercise of corresponding responsibility includes identifying, resolving, and documenting any suspicious signs of abuse or diversion for controlled substance prescriptions dispensed. A pharmacist who fails to conduct due diligence and fails to appropriately exercise their professional judgment may risk losing their license. These obligations are above and beyond the obligations of pharmacists to perform prospective drug utilization reviews for drug interactions and appropriate drug therapy. When patients are dispensed opioid prescriptions, pharmacists are the very last point of contact from anyone in the health professions. Pharmacists are the transition point between controlled substances leaving the controlled system into the general public. There is appropriate responsibility placed on pharmacies to ensure that due diligence and the exercise of corresponding responsibility is done correctly. Questions concerning safe and effective patient care invoke for a pharmacist their obligations in dispensing controlled substances. As one of the pharmacist's stated in response to the survey,

“...[f]illing a prescription at a large chain pharmacy is a dangerous proposition. There is no time to perform Drug Utilization Reviews, check OARRS, counsel patients, or perform quality Medication Therapy Management.⁶¹ The goal is to get the pills in the bottle or the injection in the arm as fast as possible. Sadly, it probably won't be long before a patient is seriously harmed or dies. Hopefully, if someone is reading this comment it won't be your son, daughter, mother, or father. Maybe you can try to do something about this retail epidemic.”⁶²

Dr. Selzer is not a pharmacist and she has no expertise in any aspect of pharmacy,⁶³ nor does she have any expertise in understanding the roles, responsibilities, practices, or policies pertinent to pharmacy as a profession or pharmacists in particular as health professionals.⁶⁴ She has no expertise in opioid abuse and diversion nor an understanding of the opioid dangers and effect on

⁶¹ It is worth noting that Dr. Selzer did not use some of the search terms mentioned by this pharmacist because Dr. Selzer, as a non-pharmacist, is unfamiliar with the terms such as OARRS. When asked if Dr. Selzer knew what the term "OARRS" (Ohio Automated Rx Reporting System) meant, she claimed no knowledge or understanding of the term. Selzer Dep. p. 78. OARRS is Ohio's Prescription Monitoring Drug Program ("PDMP") and contains a patient's controlled substance dispensing history across all pharmacies. Ohio regulations require pharmacists and prescribers to check OARRS before prescribing or dispensing controlled substances like opioids and evaluate whether the present prescription is appropriate in the context of other controlled substance prescriptions prescribed.

⁶² OBOP_0000290 at OBOP_0000363 (McNamee Ex. 14), respondent 666.

⁶³ Selzer Dep., pp. 28:24-29:1, 29:3-5, 29:6-9, 32:18-20, 32:21-23, 32:24-33:2

⁶⁴ Selzer Dep., pp. 83:14-23, 86:22-87:16; 229:18-232:1

communities.⁶⁵ As a part of her assessment, she did not seek to visit pharmacies to see how the profession of pharmacy is practiced. She has not surveyed pharmacists for any project⁶⁶. As a consequence, she relies on search terms or keywords to attempt to determine whether the pharmacy workload survey has any relationship to filing opioid prescriptions.⁶⁷ Because the questions and the free form comments did not contain a sufficient number of the terms she searched she concludes that the “review shows a decided absence of concern about opioid abuse and diversion.”⁶⁸ She did not seek to determine information about the rules and requirements for controlled substance dispensing and simply stated: “That is not my assignment. Correct.”⁶⁹ She also did not review any other articles or papers that have been published that have examined the impact of any factors on pharmacists’ practice.⁷⁰

Pharmacy Metrics

One of the questions contained in the Board of Pharmacy surveys concerns use the use of metrics.

Q.6. I feel pressure by my employer or supervisor to meet standards or metrics that may interfere with safe patient care.⁷¹

Metrics have been the subject of a number of complaints to boards of pharmacy and have been the subject of DEA enforcement actions, statements by the National Association of the Boards of Pharmacy and some Boards of Pharmacy have issued specific guidance on limitations in the use of metrics in pharmacy practice given their propensity to potentially interfere with safe patient care.⁷² As an Ohio Board of Pharmacy official testified, the Board was aware of

⁶⁵ Selzer Dep., pp. 65:12-66:8, 68:24-69:6, 83:24-84:10.

⁶⁶ Selzer Dep., pp. 28:24-29:1,29:3-5,29:6-9.

⁶⁷ Selzer Dep., pp. 75:11 – 80:9.

⁶⁸ Selzer Report, p. 2.

⁶⁹ Selzer Dep. p. 86:9-10.

⁷⁰ Selzer Dep. p. 101:3.

⁷¹ OBOP_0000112 at OBOP_0000127.

⁷² As early as February 1999, the Texas Board of Pharmacy issued a position statement on pharmacy work conditions that “discouraged employers from establishing working conditions that tend to increase the stress on dispensing pharmacists, such as setting quotas on the number of prescriptions that a pharmacist is required to dispense per hour in order to keep from being terminated or to achieve a favorable performance evaluation.” See https://www.pharmacy.texas.gov/files/pdf/BN/Feb16/Tab_19.pdf, p. 50. (Today, Kroger has 209 grocery stores across 84 cities in Texas.) For example, California prohibits pharmacies from using workflow metrics or quotas for purpose of pharmacists compensation or performance reviews. See, Ohio Board of Pharmacy Workload Advisory Committee Review and Discussion of Policy Rankings, March 31, 2022, [https://www.pharmacy.ohio.gov/documents/lawsrules/pwac/meetingmaterials/review%20and%20discussion%20of%20policy%20ranking%20exercise%20\(3.31.22%20meeting\).pdf](https://www.pharmacy.ohio.gov/documents/lawsrules/pwac/meetingmaterials/review%20and%20discussion%20of%20policy%20ranking%20exercise%20(3.31.22%20meeting).pdf); In 2013, the DEA fined Walgreens \$80M for failing to exercise its corresponding

the practice of metrics but did not understand the practice's impacts until the survey.⁷³

When asked during her deposition, what pharmacy metrics were, Dr. Selzer responded: "I have no independent knowledge of what pharmacy metrics are."⁷⁴ One of the responses noted in the open-ended section of the Ohio Board Study is the following:

884 Metrics are the most important thing to zone coordinators at Kroger - not the employees ability to take a restroom break or eat or counsel patients or assist patients in anything. 11/18/2021 8:01 PM⁷⁵

Dr. Selzer could not describe how metrics and staffing impact pharmacists and their role in opioid dispensing. Large-chain pharmacies, like Kroger, measure their stores and pharmacist performance when dispensing drugs.⁷⁶ These metrics include the number of prescriptions filled, the time it took to fill a prescription, how long a patient waited for their medications, quotas for immunizations, and customer satisfaction at the pharmacy, to name a few. In the case of Kroger, the pharmacy timed dispensing steps to a tenth of a second.⁷⁷ Metrics can be helpful for pharmacies to understand inefficiencies in their processes, but pharmacies like Kroger and other large chains have inappropriately tied metrics to pharmacist performance and compensation.⁷⁸ Of these metrics, the Ohio Board of Pharmacy determined from large chain pharmacists that pharmacy metrics most impacted patient safety, followed by inadequate staffing:

Q. And did the Board of Pharmacy in the survey also ask about pharmacy

responsibility and prevent obvious diversion of controlled substances. The DEA found that the pharmacy's compensation system created a financial incentive for pharmacists to fill prescriptions without adequately verifying their legitimacy, which contributed to the pharmacy's noncompliance with controlled substances regulations. The fine required Walgreens to stop compensating its pharmacists based on the volume of prescriptions filled. *See, <https://www.dea.gov/press-releases/2013/06/11/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under>.* In June 2013, the National Association of Boards of Pharmacy passed a resolution calling for the study of pharmacy metrics or quotas after learning that a survey conducted by the Institute for Safe Medication Practices (ISMP) found 83% of pharmacists studied believed that distractions due to performance metrics or measured wait times contributed to dispensing errors and that 49% felt specific time measurements were a significant contributing factor/. *See, <https://nabp.pharmacy/news/news-releases/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/>.*

⁷³ McNamee Dep. 41:25-42:8.

⁷⁴ Selzer Dep., p. 128:12-16.

⁷⁵ OBOP_0000290 at OBOP_0000477 (McNamee Ex. 14), p.188-89, respondent 666.

⁷⁶ June 19, 2022, Deposition of Ryan Davis (hereinafter "Davis Dep."), pp. 135:16-136:19 and 137:5-138:2.

⁷⁷ Davis Dep., p. 137:5-138:2.

⁷⁸ For a discussion of the types of performance categories Kroger measured to calculate pharmacists bonuses, see Davis Dep, pp. 246:9-250:23 and 251:4-255:21.

metrics?

A. Yes.

Q. What is your understanding of a pharmacy metric?

A. So my understanding of a pharmacy metric is that certain companies will assign, you know, a certain number of immunizations that need to be given or you need to meet your fill times in a certain percentage or you need to make certain – so essentially doing a certain amount of administrative duties, you know, per day to meet a number set by, you know, corporate.

Q. So the pharmacy metrics are not set by individual pharmacists at each store; they're set typically by the corporate headquarters. Is that true?

A. My understanding is that it's not -- it's not in control of the pharmacist that's working there.⁷⁹

The reasons why patient safety is compromised by metrics tied to performance are readily apparent, but perhaps best expressed by a Kroger pharmacist in the 2020 Survey comments, in that Kroger's metrics are "inversely proportional to patient safety:"

p.109 metrics are the worst part of retail pharmacy because the supersede anything of actual importance including pt safety. kroger pharmacy publicly states that the most important thing is patient safety but where are the metrics measuring it? where are the "back pats" or appreciation for not doing harm or having no incorrectly filled rx in a time frame? if we were to accidentally misfill an prescription all we are required to do is fill out a incident report and then it goes away until reviewed during the quarterly accuracy huddle....if our wait time or any of the following ready rate, sales, mtm percent effective, vaccines given, tech hours, medsync enrollments, savings club enrollments are not at goal we are required to have weekly conference calls until it is fixed and write up ways how we are going to fix it in a SMART format. the idea that all these metrics exist is astounding. it seems that some are inversely proportional to patient safety; for example, decreased wait time means less time spent on filling a prescription and other tasks impacting how quickly that script can be process so our patients dont have to wait a few minutes longer. Metrics have made pharmacy into a fast food like scenario and we get scolded by the patients and corporate alike if they have to wait

⁷⁹ McNamee Dep., pp. 79:15-80:14

longer. we are not treated like healthcare professionals in a healthcare setting focusing on patient safety, we are treated like a burger flipper trying to get out the next meal as quickly as possible hoping no harm comes of undercooked meat.⁸⁰

According to this pharmacist, Kroger prioritizes speed over patient safety, emphasizing increasing dispensing volume, which is directly tied to pharmacy profits. As a review of the comments section indicates, the Kroger pharmacist's comment is not novel among other pharmacists. Dispensing controlled substances requires care, sufficient time, and attention to perform due diligence. Where difficult questions exist over whether to dispense a controlled substance, corporate pharmacy policies and expectations in large-chain conflict with pharmacists' corresponding responsibilities and due diligence duties. The ability of pharmacists to properly exercise their corresponding responsibility was particularly concerning to the Ohio Board of Pharmacy.⁸¹ Pharmacy metrics, particularly those linked to pharmacist compensation or those that set unrealistic performance goals, create an incentive to dispense drugs in the face of suspicions. These concerns were shared by the Ohio Board of Pharmacy in its analysis of the survey results:

Q. Is it true that the two main leading causes for their feeling about their inability to practice safely at the pharmacy was a result of the focus on metrics and inadequate staff support?

A. Yes.⁸²

The Ohio Board of Pharmacy was especially concerned about the impact that pharmacy metrics imposed on pharmacists and their ability to perform their "corresponding responsibility."⁸³

Q. Was there a worry that pharmacists in the state of Ohio may not have the time to adequately investigate and perform their corresponding responsibilities as a result of the stressful environment in which they work and the metrics by which they are measured?

THE WITNESS: Yeah, based on the data that we were evaluating.

As the surveys demonstrate, the concerns about metrics and staffing are not isolated to single stores or limited to one large chain. Large-chain pharmacies have standardized their dispensing practices and policies across stores, ensuring consistent workflows and dispensing processes. Pharmacists at a Kroger store in

⁸⁰ OBOP_0000112 at OBOP_0000220.

⁸¹ McNamee Dep., p. 54:24-55:9

⁸² McNamee Dep., pp. 90:19-91:2.

⁸³ McNamee Dep., p. 54:24-55:9

Montgomery County, Ohio, use the same software and follow the same routines and regulations as other Kroger stores in Ohio. Additionally, because the pharmacy regulations and practice standards apply the same to all pharmacies, dispensing workflows are similar no matter the pharmacy. This standardization of large-chain pharmacy workloads helps explain the remarkably similar work experiences represented in the survey responses and comments by a cross-section of self-identifying large-chain pharmacists.

Dr. Selzer concludes “it would be an unsubstantiated leap to believe the answers to the[] questions [in the Ohio Board of Pharmacy Survey] reflect pharmacists’ specific concerns with the dispensing of opioids”⁸⁴ In my opinion it would be an unsubstantiated leap to suggest that a licensed pharmacist would *not* have controlled substances and opioids in mind when answering questions about patient safety. It is misleading to draw conclusions about whether the survey concerns controlled substances by merely counting how many times a certain term is used. This may be an appropriate method when asking questions to the general public about general opinions, it is not an appropriate method in analyzing the views of a group of licensed professionals such as pharmacists. I would not expect pharmacists or the Board to specifically list opioids or controlled substances when measuring sentiments on patient safety as all pharmacists are aware of those responsibilities and would have them in mind when completing the survey. It is part of the specialized knowledge or base that a pharmacist has in answering questions of this type and part of the specialty of the Board in reviewing the responses.

Survey Demographics

One of Dr. Selzer’s survey criticisms relates to demographic information, she notes “she cannot be certain that the opinions expressed in the data reflect a larger pool than the 2,969 licensed pharmacists working in Ohio that completed the survey.”⁸⁵ She admits that she does not know whether the results are reliable or not, she would like to see additional demographic data.⁸⁶

While certain demographic information may be relevant in evaluating certain survey results to determine whether the respondents accurately reflect a cross section of the total population to be surveyed, in the case of Ohio pharmacists in the workload survey the demographics Dr. Selzer seeks are not as relevant to the results and reliability of the survey. She states that if the Board had data such as “age, sex, and geographic region in their license database [these are] variable[s] that could have been used to weigh the data.”⁸⁷

⁸⁴ Selzer report, p. 2.

⁸⁵ Ibid.

⁸⁶ Selzer Dep, p. 189: 20-24, and p. 190:1.

⁸⁷ Ibid.

Pharmacy is a gender-neutral profession when considering the scope of practice of pharmacy; pharmacy practice roles and responsibilities; and professional requirements and adherence to practice guidelines. Goldin and Katz have written: “In sum, the position of pharmacist is probably the most egalitarian of all professions in the United States today.”⁸⁸ In addition, the age of a pharmacist does not alter pharmacy practice roles and responsibilities and professional requirements and adherence to practice guidelines.

In my opinion, there is more relevant data collected by the Board of Pharmacy concerning those who responded to the survey. The survey collected information on: the practice site for each pharmacist (large chain standalone, Large chain grocer, impatient, etc.)⁸⁹; primary role (staff pharmacist, Manager, relief pharmacist, etc.)⁹⁰; how many years a respondent has worked as a pharmacist⁹¹; how many shifts a respondent works per week⁹²; how many hours respondent works each week⁹³; number of prescriptions processed in an hour⁹⁴. These answers are far more important to the reliability of the results than the select demographic criteria that Dr. Selzer cites. Strangely, when questioned about these data points, Dr. Selzer seemed critical of the data because it was self-reported and not data from the Ohio Board of Pharmacy’s database.⁹⁵ In fact, she equated answering these questions to answers from a potential voter as to their party affiliation.⁹⁶ This is an inappropriate comparison. A pharmacist responding to its regulator has no reason to be dishonest in answering these questions and would not be. Moreover, these questions are not opinion based, they are specific demographic questions related to a respondent’s years of service, workplace and workload. Importantly, it is far more likely that the pharmacist answering the questions has more accurate information about those questions than the board of pharmacy.

Dr. Selzer’s conclusion was not that the results are inaccurate, she simply would prefer more data to gauge whether the results are an accurate assessment of all licensed pharmacists working in Ohio.⁹⁷ Her goal in assessing the survey was in part to determine whether it could be extrapolated to all pharmacists licensed in Ohio. This question is one of her own making with little relevance to the purpose the survey was issued and why it was important to conduct the survey. The survey does provide very insightful and meaningful answers to these two questions given

⁸⁸ Goldin C, Katz LF. A most egalitarian profession: pharmacy and the evolution of a family-friendly occupation. *Journal of Labor Economics*. 2016 Jul 1;34(3):705-46.

[.https://www.jstor.org/stable/26553222](https://www.jstor.org/stable/26553222)

⁸⁹ OBOP_0000112 at 134; OBOP_0000290 at 292, 293.

⁹⁰ OBOP_0000112 at 135, Q. 11.

⁹¹ OBOP_0000112 at 142, Q. 15.

⁹² OBOP_0000112 at 136, Q. 12.

⁹³ OBOP_0000112 at 140, Q. 14.

⁹⁴ OBOP_0000112 at 138, Q. 13.

⁹⁵ Selzer Dep. p. 166:4 – p. 171:17.

⁹⁶ Ibid.

⁹⁷ Selzer Report, p 14 and Selzer Dep. p. 207: 20 –208:2.

the board of pharmacy's concern about patient safety and workplace conditions. The alarming numbers of pharmacists who worked in a large grocery store setting who reported concerns about patient safety and workplace conditions which interfered with safe and effective pharmacy practice make the results both meaningful and important to a board charged with keeping the public safe through the enforcement of pharmacy regulations. A crucial element of enforcement for the Board includes evaluating whether policies and procedures in large chain grocery store settings, like Kroger, interfere with safe patient care.

The Open-ended Questions Substantiate the Validity of the Ohio Board of Pharmacy 2020 & 2021 Pharmacist Workload Surveys

A significant number of respondents to the Ohio Board of Pharmacy surveys also took the time to write a comment in the open text field. There were 2,969 respondents to the 2021 survey and 1,223 respondents, or about 41% of those who responded wrote comments. In 2020 there were 4,159 respondents and 1,412 or 34% that left a comment.⁹⁸ In my opinion this is a significant number of respondents that felt strongly enough about the issues to leave a comment. In many cases the comments were whole paragraphs expressing extremely strong and consistent views.

The Ohio Board of Pharmacy found comments are fairly consistent across the respondents in the chain setting:

Q. Okay. Now, we've selected some comments over the course of this examination. I'm certainly not going to read them all. Are these comments fairly consistent across the respondents in the survey, that people are expressing concern about metrics, expressing concern about workload and expressing a concern about patient safety in the chain pharmacy and chain grocery settings in Ohio?

Q. Mr. McNamee, I didn't hear your answer.

A. Oh, sorry. Yes.⁹⁹

The comments are replete with concerns for patient safety, unsafe working conditions and serious concerns about safe and effective patient care. In my review of the comments provided in both surveys, I found numerous comments that demonstrate unsafe workloads which would have an impact on the safe administration of controlled substances and other pharmacy tasks. There were repeated references to "patient safety", "metrics", "inadequate breaks", "stress" and/or "anxiety", "mental Health", "mistakes" and/or "errors" and "workload" can be found throughout the comments. Notably, the term "suicide" is even mentioned

⁹⁸ OBOP_0000112 at OBOP_0000116.

⁹⁹ McNamee Dep. 102:25 – 103:15

by, a survey participants.¹⁰⁰ This was a courageous commentary for a pharmacist struggling with the stress of workforce demands:

556 "It is deplorable to work as a pharmacist. I have completely left this profession after 25 years of suffering because of unethical and harmful working conditions. I am like others are tired of not having any pressure on companies to regulate them to increase staffing and allow better working conditions so we are not jeopardizing our families and livelihoods of our patients. Enough is enough. There's just too much corporate greed at the cost of pharmacists' licenses. I have been depressed that I can no longer work in a pharmacy. I have attempted suicide and my family has suffered due to my illness. Please do something for the future of pharmacy professionals. I had so many dreams which are no longer able to accomplish. There are so many pharmacists walking in depressed state of mind. Please regulate the profession. We are not dispensing candies. This is a life and death daily. Pharmacists are number 11 on a suicidal list of professions. If Boards will not come up with laws to improve work then who will. Fining corporations is not enough when they are profiting billions."¹⁰¹

Table 1 contains a non-exhaustive list that I drafted of the various tasks that a pharmacist must perform each day as part of their responsibilities. The requirements that are listed in Table 1 are not additive when considered in total, they are synergistic in their effect upon every other task in a pharmacist's daily professional responsibilities. The second item in Table 1 is the prescription drug monitoring program that is seen in the Ohio OARRS Rules for Pharmacists.²² These rules apply to every pharmacist filling any controlled substance prescription. Table 2 lists the OARRS requirements for all controlled substance prescriptions in Ohio.¹⁰² Again, Dr. Selzer was unaware of what OARRS is and stated that this was not part of her assignment.¹⁰³ In my view, the dispensing requirements and subsequent impact upon opioid dispensing and required monitoring are inherent in any consideration of the workload impact and stresses for pharmacists.

Dr. Selzer and the Validity of the Survey

Dr. Selzer did not discuss or examine whether there were other indications that the large-chain pharmacist survey responses and comments were valid, reliable and creditable. First, the Ohio Board of Pharmacy's determination that the results were reliable cannot be overstated.¹⁰⁴ A regulator that licenses, inspects, investigates, regulates, monitors, and disciplines pharmacies and pharmacists possesses significant expertise in how pharmacies operate. The Board's characterization of the survey findings as reliable and "striking" should be

¹⁰⁰ McNamee Ex. 14, OBOP_oooo449.

¹⁰¹ McNamee Ex. 14.

¹⁰² The list contains the minimum requirements for checking OARRS. Pharmacist may and often will check OARRS more frequently than required.

¹⁰³ Selzer Dep. 78:22-79:5

¹⁰⁴ McNamee Dep., pp. 68:2-4, 110:5-15

given substantial weight. Importantly, the survey findings suggested that a significant portion of Ohio pharmacists who responded failed to comply with critical regulatory requirements for safe and effective dispensing. These findings compelled the Board to form an advisory group to study workload concerns further and make policy recommendations.¹⁰⁵

Q. Was there a concern at the Ohio Board of Pharmacy that the number of prescriptions that were being filled, the staffing levels that existed in the pharmacy and the metrics employed by large chain pharmacies and large chain grocery stores posed a risk to patient safety?

THE WITNESS: Yes.¹⁰⁶

Dr. Selzer did not review the policy recommendations of the workload advisory committee or other steps the Ohio Board of Pharmacy took in response to the survey results.¹⁰⁷ The "striking" results, which Ohio Board of Pharmacy defined as "considerable issues,"¹⁰⁸ compelled the Board to form a study committee to develop and evaluate regulatory options to address patient safety concerns. Based on its review of survey responses and comments, the Ohio Board of Pharmacy grouped pharmacists concerns and offered policy solutions to each concern. Of the various policy options, pharmacists overwhelmingly believed prohibiting metrics from evaluating pharmacist performance would improve patient safety.¹⁰⁹ The Board modeled this regulatory rule after California, which introduced regulations to improve patient safety.¹¹⁰

The workload committee's policy recommendations further support the survey findings' validity, credibility, and reliability, as logically, the committee would only make policy recommendations for those workload concerns it determined were valid, credible, reliable, and significant. The policy recommendations formulated by the workload advisory committee focused on eliminating metrics in the evaluation and compensation of pharmacists and enforcing appropriate staffing levels to adequately perform work safely and effectively, all in the service of ensuring patient safety.¹¹¹

It is worth noting that several large-chain pharmacy representatives, including Kroger, sat on the workload advisory committee and participated in its work.¹¹² According to the Ohio Board of Pharmacy, none of the large chain pharmacies objected to the surveys. In fact, it was the workload advisory

¹⁰⁵ OBOP_oooo00112

¹⁰⁶ McNamee Dep., pp. 89:19-90:2.

¹⁰⁷ Selzer Dep., pp. 106:5-107:6.

¹⁰⁸ McNamee Dep., p. 112:19-25.

¹⁰⁹ McNamee Dep., pp. 169:15-171:13 and 172:3-18.

¹¹⁰ Id. at pp. 169:15-171:13.

¹¹¹ McNamee Dep., pp. 154:8-156:6 and 90:19-91:2.

¹¹² McNamee Dep., pp. 117:3-118:16

committee that recommended conducting a follow-up survey in 2021.¹¹³ Presumably, concerns about reliability and credibility, or any other survey deficiencies, could have been cured by the workload advisory committee at the direction of the member large-chain pharmacies if any such concerns were expressed

Dr. Selzer writes in her report: "Validity, then, is the crux of the matter for this survey."¹¹⁴ Dr. Selzer did not review any other pharmacy workload surveys for either her report or for her deposition. One method of proven value for survey research validity assessment is to compare results from one survey to similar surveys that are assessing the same issues. Surveys by other state pharmacy boards, national pharmacy organizations, and news media reports provided information consistent with the Ohio Board of Pharmacy's results. Dr. Selzer acknowledged she could not locate these surveys and had limited knowledge of other surveys. Had Dr. Selzer found the other surveys, she may have looked beyond the data of the Ohio survey and begun to formulate a richer understanding of how workloads impact the safe dispensing of controlled substances. An exhibit to the deposition of the Board of Pharmacy representative, which Dr. Selzer stated she read, the Missouri Board of Pharmacy workload survey¹¹⁵ posed almost identical questions to the Ohio survey. Significantly, highly similar questions resulted in highly similar responses. Also noteworthy are the similarities between comments of Missouri pharmacists about how metrics and staffing impact patient safety. One comment from a Missouri pharmacist captures many concerns that many Ohio pharmacists would later express:

Usually there are close to anywhere from 160-200 prescriptions processed and filled during that time with one pharmacist. And I'm expected to counsel, promote and give immunizations, monitor adherence for Star ratings, provide OTC consultations, answer phones, supervise technician staff and answer their questions, answer telephone questions from patients, physicians and nurses, take new phone in prescriptions, check the POMP and evaluate all opioid prescriptions, among several other work duties. We're understaffed due to technician and pharmacist hours being cut, and we are constantly told we don't work fast or efficient enough, or give enough immunizations. Each day we receive emails with our "goals" that really aren't "quotas," but it's clear we have set numbers to reach. These emails have the numbers highlighted in green, yellow, and red like a stoplight for those stores in the market who are/aren't reaching the company "goal." I've been told directly by my district manager that "our company can flex its muscle like this because we know the market is saturated and there are no other jobs for pharmacists; so we can ask all of

¹¹³ McNamee Dep., pp. 245:1-246:9.

¹¹⁴ Selzer Report, p. 6, paragraph 2.

¹¹⁵ McNamee Dep., pp. 31:17-32:5

this of you and you have no choice but to do it." This was the answer to my concerns about work safety. I do not speak up about it anymore because I'm afraid they'll replace me with a younger colleague who's eager to make money right out of school and will work readily in this ridiculous environment. Safety is not the priority. Customer service is not the priority. Numbers and metrics are. It's very stressful and I've come to resent my profession, yet fear for my job. And my job satisfaction is low and team morale is terrible because we work in a circus-like environment and can't possibly provide the excellent service we'd like to. But my utmost concern is that I will make a dispensing error and injure a patient.¹¹⁶

Like the Ohio survey, the Missouri survey did not ask specifically about opioids. Yet, some pharmacists recognized that the workload pressures they face impacted their ability to dispense controlled substances safely. Results from the Missouri survey (N=986)¹¹⁷ found the following:

- 51.8 percent of respondents either disagreed or strongly disagreed with the following statement: I have adequate time to complete my job in a safe and effective manner.
- 64.1 percent of respondents either disagreed or strongly disagreed with the following statement: I am given sufficient time away from the pharmacy for lunch or rest breaks during my shift to allow me to safely provide patient care.

This comparison of Missouri and Ohio survey results confirmed the growing trend that workload demands are affecting patient safety¹¹⁸ For example,

Missouri Board of Pharmacy Survey	Ohio Board of Pharmacy Survey
Q1. I have adequate time to complete my job in a safe and effective manner. ¹¹⁹ <u>Disagree responses for all respondents 51.8%</u>	Q1. I feel that I have adequate time to complete my job in a safe and effective manner. ¹²⁰ <u>Disagree responses for all respondents 60.83%, Disagree responses by Large Chain Grocer 88.05%.</u>
Q3. My practice site has sufficient pharmacist staffing to safely provide patient care. ¹²¹ <u>Disagree responses for all respondents 45.7%.</u>	Q3. I feel that my work environment has sufficient pharmacist staffing that

¹¹⁶ OBOP_0002207 at 2233 (McNamee Ex. 4)

¹¹⁷ OBOP_0002207 at 2208 (McNamee Ex. 4)

¹¹⁸ OBOP_00000112 (McNamee Ex. 10). p. 1

¹¹⁹ OBOP_0002209

¹²⁰ OBOP_00000112 at OBOP_00000117; OBOP_0000290 at 294-298;

¹²¹ OBOP_0002211

	allows for safe patient care. ¹²² <u>Disagree responses for all respondents 68.61%, Disagree responses by Large Chain Grocer 81.98%.</u>
Q2. My practice site has sufficient technician staffing to safely provide patient care. ¹²³ <u>Disagree responses for all respondents 57.2%.</u>	Q4. I feel that my work environment has sufficient pharmacy technician staffing that allows for safe patient care. ¹²⁴ Disagree responses for all respondents 75.71%. <u>Disagree responses by Large Chain Grocer 86.46%.</u>
Q6. I feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care at my practice site (e.g., mandatory dispensing or immunization requirements). ¹²⁵ <u>Agree responses for all respondents 59.6%</u>	Q6. I feel pressure by my employer or supervisor to meet standards or metrics that may interfere with safe patient care. ¹²⁶ <u>Agree responses for all respondents 58.91%, Disagree responses by Large Chain Grocer 62.76%.</u>

As a result of the 2019 Missouri Board of Pharmacy survey, the following was provided in a Missouri Board of Pharmacy Statement on Pharmacy Working Conditions¹²⁷:

“4. Permit holders should immediately review any requirements or policies that may inhibit safe patient care. This includes any dispensing or vaccination metrics/requirements that place unreasonable expectations on pharmacy staff (e.g., # of prescriptions or vaccines per hour). The Board is particularly concerned with pharmacy metrics and requirements that do not give pharmacists sufficient time to perform needed clinical services. While the Board recognizes business needs, patient safety should not be jeopardized for company profits.”

Two surveys conducted by the American Pharmacist Association demonstrate concerns by pharmacist with their workload and patient safety and stress over

¹²² OBOP_00000112 at OBOP_00000121; OBOP_0000290 at 299-303

¹²³ OBOP_0002210

¹²⁴ OBOP_00000112 at OBOP_00000123; OBOP_0000290 at 304-308.

¹²⁵ OBOP_0002212

¹²⁶ OBOP_00000112 at OBOP_00000127; OBOP_0000290 at 314-318.

¹²⁷ Missouri Board of Pharmacy Board Statement on Pharmacy Working Conditions (4-29-2021). [https://pr.mo.gov/boards/pharmacy/covid-19/WorkingConditions\(FINAL\).pdf](https://pr.mo.gov/boards/pharmacy/covid-19/WorkingConditions(FINAL).pdf), accessed 14 February 2023.

time.¹²⁸ Table 3 compares responses to 3 crucial questions posed in the Ohio Board of Pharmacy Pharmacist Workload Survey with results from the APhA/NASPA National State Based Pharmacy Workplace Survey.²⁷ These three questions deal with adequate time to complete job safely, sufficient pharmacist staffing to allow for safe patient care, and work environments having sufficient pharmacy technician staffing to allow for safe patient care. Comparing the average scores for these three questions results in a cumulative difference of only 1.67%. This speaks to the validity of both of these surveys in assessing the issues they examined. The final report of the APhA/NASPA survey affirmed that “most of the factors of concern that were identified by this survey are systems based and changes are under the direct control of the employer/management. For the profession, the stress and workplace conditions explored in the survey findings are having a negative impact on the ability to recruit, train, and retain pharmacy personnel.”¹²⁹

The APhA/NASPA survey was promoted via email, periodicals, and social media; therefore, it did not use a random sample of individuals. One of the strengths of the study was its large sample size, 4,482. The consistency between the responses in the APhA surveys and the Ohio Board of Pharmacy survey reinforces the validity and reliability of the Ohio survey results. Another study in 2021 by Clabaugh et al. examined working conditions in community pharmacies and also had a large sample of 1,222 participants. This study was a convenience sample study.¹³⁰ The results in this study are similar to the findings shown in Table 3 below. In both the APhA/NASPA and the Clabaugh study on workplace pharmacy issues, the authors validate the creditability and reliability of the studies’ similar findings on the basis of larger sample sizes and mixed survey designs. These statements in both documents reinforce the validity of the Ohio Board of Pharmacy survey.

The Ohio Board of Pharmacy confirmed the similarity in the various survey results:

Q. Okay. And you've looked at the results of the Missouri survey. You've looked at the New York Times article. You looked at the Chicago Tribune article. You looked at survey

¹²⁸ https://www.aacp.org/sites/default/files/2020-03/2019_NPWS_Final_Report.pdf; <https://www.aacp.org/sites/default/files/finalreportofthenationalpharmacistworkforcestudy2014.pdf>

¹²⁹ APhA/NASPA NATIONAL STATE-BASED PHARMACY WORKPLACE SURVEY, 2021. <https://s3.amazonaws.com/filehost.pharmacist.com/CDN/PDFS/National%20State-Based%20Pharmacy%20Workplace%20Survey%20Final%20Report%20APRIL%202022-FINAL.pdf?AWSAccessKeyId=AKIAYICBVAN2V7IWVG4T&Expires=1675697917&Signature=xJcMX6hszQWW1lOlt5RxK58ldFo%3D>. accessed 6 February 2023.

¹³⁰ Clabaugh M, Newlon J, Plake K. Perceptions of working conditions and safety concerns in community pharmacy. *Journal of the American Pharmacists Association* 61 (2021) 761-771. <https://doi.org/10.1016/j.japh.2021.06.011>

results from the American Pharmacists Association. Were the results that you received in Ohio consistent with the results that you were reading about on a national basis?

THE WITNESS: Yes¹³¹

Most importantly, the survey results were reliable enough that Kroger decided to conduct its own survey of its employees and used similar questions as the Ohio Board of Pharmacy Workload surveys.¹³²

Kroger Survey

Kroger asked its pharmacists whether “overall, there is adequate staffing at my pharmacy that allows safe patient care?” 41% of Kroger pharmacists responded that they strongly disagreed and 35% disagreed. As a result, 76% felt staffing was inadequate for safe patient care.¹³³ Additionally, 80% of Kroger respondents felt physically exhausted and 76% felt emotionally exhausted because of their work.¹³⁴ 77% felt that the workload did not allow them to get everything done in a safe, satisfactory manner.”¹³⁵ These responses are similar to the Ohio Board of Pharmacy survey findings for large chain grocery sites.

Many of the Kroger comments in their internal survey are consistent with the comments expressed by respondents in the Ohio Board of Pharmacy workload study. Some examples include:

[C]utting hours and expecting more work feels very dangerous to me. I don't feel like patient safety is a priority to corporate. I feel they are more concerned with numbers and speed than safety. As a pharmacist I feel extremely rushed to do the duties I am responsible to complete in a day. I don't feel like I am able to create the type of patient interactions that foster pertinent questions from patients.¹³⁶

I think we need more technician and pharmacist hours to prevent medication errors from happening. Kroger is requiring more and more of their staff and continually cutting hours while requiring more.¹³⁷

The Kroger survey results were not shared with Dr. Selzer.¹³⁸

¹³¹ McNamee Dep., p. 115:11-22.

¹³² Davis Dep. p. 269:7 – p. 270:8.

¹³³ KrogerWVAooo24851.

¹³⁴ KrogerWVAooo24852.

¹³⁵ Ibid.

¹³⁶ KrogerWVAGooo24849 at 24858 (emphasis in the original).

¹³⁷ Ibid. (emphasis in the original).

¹³⁸ Selzer Dep. p. 177:3-12

Conclusion

In my opinion the 2020 and 2021 pharmacy workload surveys conducted by the Ohio Board of Pharmacy are valid and reliable. Tasked with regulating the practice of pharmacy and following the growing concerns of work conditions, the Board sought to collect and analyze survey responses to highlight whether pharmacy metrics continue to create unsafe work environments. The survey was administered directly to Ohio pharmacists and collected anonymous responses. This method encouraged candid feedback and facilitated a safe avenue for pharmacists to provide their concerns without risk of retaliation.

The surveys utilized appropriate survey design and research techniques and methodology consistent with the Board's goals. The series of questions drafted by the Board examined whether pharmacy workload impacts pharmacists' ability to adequately exercise their corresponding responsibility. Analyzing the survey results and pharmacists' comments highlight how pharmacy work environments impact dispensing and patient safety. The information obtained from pharmacists, particularly those working in large chain grocery stores, proved "striking" to the Board, which responded with further study the concerns. The survey information, when placed in the context of regulatory obligations of controlled substances, pharmacy practice and the ongoing opioid epidemic, were persuasive. Data from the surveys indicates that pharmacists working in large chain grocery stores believe their employers' policies and procedures, workload tasks, metrics and staffing levels in their workplace impact patient safety. The Pharmacy Workload Advisory Committee recommendations developed from the surveys responses were appropriate and reasonable policy solutions that effectively addressed the concerns identified in the surveys' findings. Those same policy considerations, some of which are mandated by other states, will require adjustments to internal pharmacy procedures and practice to improve safe patient care.

Respectfully submitted,



Jack Fincham
Executed on February 17, 2023

Table 1.
Ohio Retail Pharmacists Requirements

Adequate time to complete all necessary tasks
Adequate time to accurately verify prescriptions
-For any dispensing of a controlled substance prescription: --State of Ohio OAARS Rules for Pharmacists (OAC 4729:5-5-08) ¹³⁹
Time to counsel patients on proper use of dispensed medications
Reconstitution of medications
Drug Utilization Reviews (DURs)
Medication therapy management (MTMs) for Medicare Part D ¹⁴⁰
Contacting insurers to obtain prior authorization approval for restricted medications
Contacting physicians/prescribers for verification of prescription orders
US FDA REMS [Risk Evaluation and Mitigation Strategies (REMS)] requirements for certain drugs, requires website access and/or phone contact for approval to dispense the medications ¹⁴¹
Preparing and administering vaccinations and other non-dispensing functions
Phone contact with patients, health care providers, insurers, pharmacy benefit management ¹⁴² entities
Generic substitution for applicable medications
Monitor inventory and place orders to avoid shortages
Converting prescriptions to 90 days supplies versus 30 days
Adequate staff for assistance -Review all pharmacy technician preparations for accuracy before dispensing prescriptions to patients.
Ability to focus
Ability to take breaks -Meals -Comfort (use restroom)
12 plus hour shifts
No requirement for working unpaid hours

¹³⁹ OAARS Rules for Pharmacists, <https://www.pharmacy.ohio.gov/Documents/LawsRules/RuleChanges/OARRSRules/W hen%20to%20Check%20OARRS%20-%20One%20Pager%20-%20Pharmacists.pdf>, accessed 4 February 2023.

¹⁴⁰ Medicare Part D Medication Therapy Management. <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover/medication-therapy-management-programs-for-complex-health-needs>. Accessed 4 February 2023.

¹⁴¹ US FDA Roles of Different Participants in REMS. <https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems>, accessed 4 February 2023

¹⁴² NAIC. Pharmacy Benefit Managers, <https://content.naic.org/cipr-topics/pharmacy-benefit-managers>, accessed 3 February 2023.

Table 2.
OARRS Rules for Pharmacists¹⁴³

 STATE OF OHIO BOARD OF PHARMACY	
OARRS RULES FOR PHARMACISTS (OAC 4729:5-5-08)	
<p>Prior to dispensing an outpatient prescription for a controlled substance, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:</p>	
<p> RULE 1: A patient adds a different or new controlled substance drug to their therapy that was not previously included.</p> <p>What this means: The first time you fill a prescription for a new or different controlled substance, you must run an OARRS report. First hydrocodone? Run it. Next day new RX for testosterone? Run it again. A week later another hydrocodone? Not required, but a good idea.</p>	<p> RULE 4: A patient is from outside the usual pharmacy geographic area.</p> <p>What this means: Why did that patient drive so far to go to your pharmacy?</p>
<p> RULE 2: An OARRS report has not been reviewed for that patient during the preceding 12 months, as indicated in the patient profile.</p> <p>What this means: If you don't have a documented record of having run an OARRS report in the past year, run it. This creates your baseline.</p>	<p> RULE 5: A pharmacist has reason to believe the patient has received prescriptions for controlled substances from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location (i.e. same group practice).</p> <p>What this means: A review of a patient in the pharmacy dispensing system indicates the patient is visiting multiple prescribers in the past three months that are not part of the same group practice based on physical location.</p>
<p> RULE 3: A prescriber is located outside the usual pharmacy geographic area.</p> <p>What this means: Why did that patient drive so far to go see that prescriber?</p>	<p> RULE 6: Patient is exhibiting signs of potential abuse or diversion. (This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.)</p> <p>What this means: The occasional early refill may be warranted. Patients may need to refill their medication before they go on a vacation. But to refill early every month just because the insurance will pay for it at a 75% exhaust level allows a patient to stockpile medications, increasing the chance of an unintentional overdose. Watch for accumulation of drugs.</p>
<p>Remember: To be valid, a prescription must be issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber's practice. The responsibility for the proper prescribing is upon the prescriber, however a corresponding responsibility also rests with the pharmacist who dispenses the prescription. Pharmacists shall use professional judgment when making a determination about the legitimacy of a prescription.</p> <p>A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin [OAC 4729:5-08 (G), 4729:5-5-10 (A), & 4729:5-5-15 (A)].</p>	<p>If in doubt, run the OARRS report. You don't know what you don't know.</p> <p>It's OK to say no. You might just save a life.</p>

¹⁴³ BOP_MDL1144969,

<https://www.pharmacy.ohio.gov/Documents/LawsRules/RuleChanges/OARRSRules/W hen%20to%20Check%20OARRS%20-%20One%20Pager%20-%20Pharmacists.pdf>

Table 3. Comparison of Data Between Ohio Survey and APhA/NASPA Survey

Source of Data		Ohio BOP 2021 RPh Workload Survey ²	Disagreeing %	APhA/NASPA NATIONAL STATE-BASED PHARMACY WORKPLACE SURVEY ¹⁴⁴	Disagreeing %
Item on Survey	I have adequate time to complete my job in a safe and effective manner.	Question 2 ¹⁴⁵	70.83	Item on page 11, item 3	75.31
	Sufficient pharmacist staffing that allows for safe patient care.	Question 3 ²	69.15	Item on page 11, item 6	70
	I feel my work environment has sufficient pharmacy technician staffing that allows for safe patient care.	Question 4 ²	75.31	Item on page 11, item 2	75

¹⁴⁴ APhA/NASPA NATIONAL STATE-BASED PHARMACY WORKPLACE SURVEY, 2021. <https://s3.amazonaws.com/filehost.pharmacist.com/CDN/PDFS/National%20State-Based%20Pharmacy%20Workplace%20Survey%20Final%20Report%20APRIL%202022-FINAL.pdf?AWSAccessKeyId=AKIAYICBVAN2V7IWVG4T&Expires=1675697917&Signature=xJcMX6hszQWW1lOlt5RxK58ldFo%3D>. accessed 6 February 2023.

¹⁴⁵ McNamee Ex. 14.